

Mandible reconstruction using patient-specific pre-bent reconstruction plates: comparison of standard and transfer key methods

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Abstract

Purpose Mandible reconstruction with reconstruction plates requires bending the plates during the operation and fixation using the “standard method” (ST-method). The ST-method is limited when a pathological process has perforated the mandibular outer cortex. A transfer key method (TK-method) was developed where plates are pre-bent using a patient-specific mandible model and positioned on the mandible with the help of transfer keys. The ST-method and TK-method were compared in a clinical trial.

Methods Mandibular reconstruction was performed on 42 patients in this study: 22 were performed using the TK-method and 20 using the ST-method. Pre- and postoperative CT scans were evaluated by measuring the distances between six corresponding landmarks on the mandibular condyles and rami. The difference between pre- and postoperative distances was used to evaluate reconstruction accuracy.

Results The median deviation of the unsigned/ absolute values of all six distances was 1.07 mm for the TK-method and

1.67 mm for the ST-method. The TK-method showed significantly better results. For the signed values, the median deviation of the six distances was -0.6 mm for the TK-method and -1.47 mm for the ST-method, indicating that the mandibles became narrower with both methods. This width difference was not statistically significant.

Conclusion The TK-method was more accurate than the ST-method in a clinical trial. The TK-method was effective and accurate for mandible reconstruction using pre-bent fixation plates.

Keywords Mandible reconstruction · Pre-bent mandible reconstruction plates · Pre-formed mandible reconstruction plates · Patient Specific Implants · Mandible STL models · CT measurements

Introduction

The mandible plays a key role in masticating food, swallowing and speaking and supports the tongue, which allows the respiratory tract to stay open. Moreover, it is vital for the harmonious appearance of the face [1–5]. With many oral diseases such as carcinomas, osteoradionecrosis, osteomyelitis and bisphosphonate-related jaw necrosis, a mandibular continuity resection is often unavoidable. Mandible reconstruction after such resections remains a complex and time-consuming task for the surgeon. In addition to the rehabilitation of the mandible contour, the reconstruction of the occlusion and the correct position of the temporomandibular joint condyles in the glenoid fossae are crucial for providing the patient with a masticatory function and an aesthetically satisfying result. To achieve this, there are currently two principal methods for primary mandibular reconstruction after segmental continuity resection of the mandible:

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- alloplastic mandibular reconstruction using angular-stable locking mandibular reconstruction plates and secondary osseous reconstruction of the defective area after a recurrence-free interval;
- osseous reconstruction immediately after resection in combination with angular-stable locking reconstruction plates or miniplates.

Most clinics today use angular-stable locking reconstruction plates and bend the plates only during surgery according to the clinical needs. In this procedure, referred to here as the “standard method” (ST-method), the reconstruction plate is bent according to the existing contour of the mandible prior to the continuity resection. After the plate is bent and positioned, it is fixed onto the mandibular bone with a minimum of four screws, two in the distal and two in the proximal segments of the planned continuity resection. The position of the plate on the mandible is thus clearly set. The plate is then removed and the relevant mandible segment resected. Following the resection, the plate can be repositioned on the two remaining mandibular stumps by using the screw holes of the primary plate fixation. Current standard screw-plate systems with angular stability allow for an almost complete three-dimensional (3D) reconstruction of the mandible [6–9]. As an alternative to intraoperative bending, the plates can be pre-bent using a patient-specific mandible model created with the help of rapid prototyping. The plates are sterilized and implanted during the operation according to the ST-method [6, 10–14].

The ST-method, however, has limitations or is inapplicable if the mandibular outer cortex is involved in the pathological process that necessitates the resection, or if a primary microvascular bone flap (e.g., fibula, scapula or iliac crest) is planned [1–10].

To address these problems, several methods have been published over the years which are applicable even if the outer cortex is no longer intact [1, 15–23]. We believe, however, that these methods are often complicated and time-consuming.

In the present study, a transfer key method (TK-method) is clinically validated using preoperative and postoperative computed tomography to determine the accuracy of the postoperative position of the ascending rami and the condyles in comparison with the above-mentioned standard method (control group).

In addition to radiological validation, postoperative occlusion was used as clinical parameter to evaluate reconstruction accuracy.

A trial performed by Wilde et al. [6] showed that, on a model, the TK- and ST-methods achieved an equal level of reconstruction accuracy. The objective of our study was thus to examine whether the TK-method could achieve acceptable

reconstruction outcomes in clinical practice in comparison with the ST-method.

Methods

In the TK-method mentioned above, a reconstruction plate was pre-bent on a patient-specific 3D mandible model. Before the plates were pre-bent, the models were usually modified for each patient by removing material, especially in the chin region and the sides of the body of the mandible with a burr (Fig. 1a). The models of the few patients undergoing primary osseous reconstruction (Table 1) were modified in such a way that their form corresponded to the desired outcome of primary osseous reconstruction. This procedure and the rationale behind it will be explained in detail in the discussion.

After pre-bending, the plates were fixed onto the model with angular-stable locking screws in the desired position. In order to find the model position in the operating room, transfer keys at the distal ends of the plate were manufactured from a light-curing resin (Fig. 1). The plates and the transfer keys were then sterilized for the operation. The mandibular continuity resection could thus be performed during surgery without any further measures. The transfer keys were positioned on the mandibular bone and used to determine the

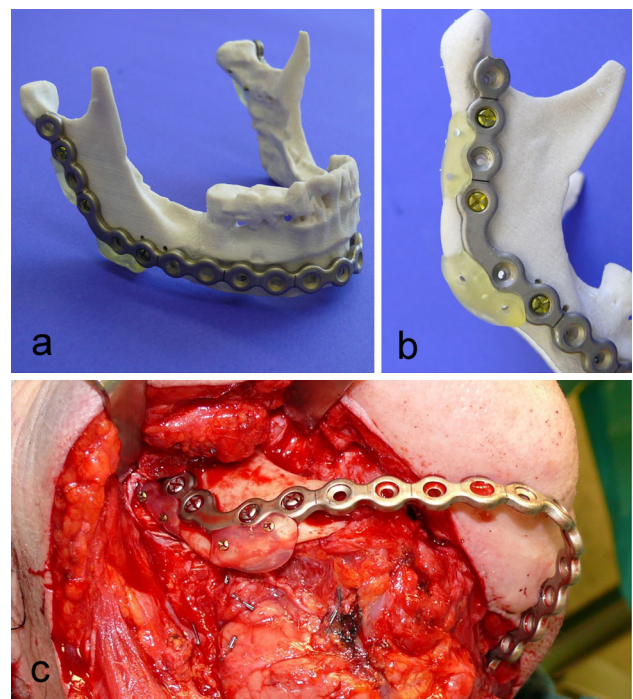


Fig. 1 **a** Mandibular reconstruction plate pre-bent on a model and fixed with screws; **b** transfer keys on patient-specific mandibular model; **c** intraoperative image taken after the plate was fixed to the remaining mandible stump using transfer keys

position of the mandibular reconstruction plate. In this position, the plate was fixed intraoperatively onto the remaining mandibular stumps in accordance with the position on the model (Fig. 1).

A group of operations that were performed according to the ST-method described in the introduction served as a control group.

In order to fabricate patient-specific mandible models, the DICOM data of a CT data set were transmitted via a password-protected FTP server to a commercial supplier (Phacon, Leipzig, Germany). This company used the data set to segment the mandible with their in-house software. The data set was then converted into the Standard Tessellation Language format (STL format) and sent to a 3D printer

Table 1 Overview of patients and operations

Patient	Gender	Pathology	Included operations	Defect type	Group	Plate type	Bending	Recon type	Measured distances	Number measured distances
1	F	BRONJ	1	AG-LB	TK	MM	Pre	ap	ABCDEF	6
2	F	MALG	2	AG-LB	TK	MM	Pre	ap	ABCDE	5
3	M	MALG	3	LB-SD-LB	TK	MM	Pre	ap	ABCDEF	6
			4	LB-SD-LB	TK	MM	Pre	ap	ABCDEF	6
4	M	ORN	5	AG-LB-CP	TK	MM	Pre	ap	ABD	3
5	M	MALG	6	AG-LB	ST	UL	Pre	ap	ABCDEF	6
			7	AG-LB-SD	TK	MM	Pre	ap	ABCDEF	6
6	F	MALG	8	AG-LB	TL	MM	Pre	ap	ABCDEF	6
7	M	BRONJ	9	AG-LB-CP	TK	MM	Pre	ap	ABCDF	5
8	F	MALG	10	AG-LB-SD	TK	MM	Pre	ap	ABCDEF	6
9	M	MALG	11	LB-SD	TK	MM	Pre	ap	ABCDEF	6
10	M	MALG	12	AG-LB	TK	MM	Pre	ap	ABCDEF	6
11	M	MALG	13	AG-LB-SD	ST	MM	Pre	ap	ABCDEF	6
		PF	14	AG-LB-SD	TK	MM	Pre	ap	ABCDEF	6
12	M	MALG	15	RA-AG-LB-SD-CP	TK	MM	Pre	v Fib	ABC	3
13	F	MALG	16	RA-AG-LB	TK	MM	Pre	ap	ABCDF	5
14	M	BRONJ	17	RA-AG-LB-SD-LB-AG-RA	TK	MM	Pre	ap	ABCDEF	6
15	M	MALG	18	CP-RA-AG-LB	TK	MM	Pre	ap	ABC	3
16	M	MALG	19	LB-SD	TK	MM	Pre	v IC	ABCDEF	6
17	F	MALG	20	LB-SD-LB	TK	MM	Pre	ap	ABCDEF	6
18	M	ORN	21	LB-SD	TK	UL	Pre	ap	ABCDEF	6
19	F	BRONJ	22	AG-LB-SD	TK	UL	Pre	ap	ABCDE	5
20	M	ORN	23	CP-RA-AG-LB	ST	UL	Intra	ap	ABC	3
			24	CP-RA-AG-LB-SD	TK	UL	Pre	ap	ABC	3
			25	CP-RA-AG-LB-SD	ST	MM	Pre	ap	ABC	3
21	M	ORN	26	AG-LB-SD	TK	LM	Pre	ap	ABCDEF	6
22	M	OSTM	27	AG	ST	MM	Pre	ap	ABCDEF	6
23	M	MALG	28	CP-AG-LB	ST	MM	Pre	ap	ABCF	4
24	F	BRONJ	29	AG-LB-SD-LB	ST	MM	Pre	v Fib	ABCDF	5
25	M	ORN	30	AG-LB	ST	UL	Pre	ap	ABC	3
			31	AG-LB-LB-AG	ST	MM	Pre	ap	ABC	3
26	M	OSTM	32	LB	ST	MM	Pre	ap	ABCDEF	6
27	F	MALG	33	CP-AG-LB-SD	ST	MM	Pre	ap	ABCDF	5
28	F	AM	34	CP-RA-AG-LB	ST	MM	Pre	nv IC	ABC	3
29	F	MALG	35	LB-SD	ST	MM	Pre	ap	ABCDEF	6
30	M	MALG	36	AG-LB	ST	MM	Pre	ap	ABC	3
31	M	MALG	37	CP-RA-AG-LB	ST	MM	Pre	ap	ABCD	4
32	M	MALG	38	CP-RA-AG-LB	ST	MM	Pre	ap	AB	2
33	M	MALG	39	LB	ST	UL	Pre	ap	ABCDEF	6
34	M	MALG	40	RA-AG-LB-SD	ST	UL	Pre	ap	ABCDE	5

Table 1 continued

Patient	Gender	Pathology	Included operations	Defect type	Group	Plate type	Bending	Recon type	Measured distances	Number measured distances
35	F	BRONJ	41	AG-LB	ST	MM	Intra	ap	ABCDEF	6
36	F	BRONJ	42	RA-AG-LB-SD	ST	UL	Intra	ap	AB	2

Patients 3, 5, 11, 14, 20 and 25 had multiple operations that we were able to analyze.

Gender: F = female; M = male

Pathology: MALG = malignoma; BRONJ = bisphosphonate-related osteonecrosis of the jaw; AM = ameloblastoma, ORN = osteoradionecrosis; OSTM = osteomyelitis; PF = plate fracture

Defect type: SD = symphysis defect; LB = lateral body defect; AG = angle defect; ramus defect; CP = resection of the coronoid process

Group: ST = standard method; TK = transfer key method

Plate type: MM: Matrix Mandible Recon; UL = Unilock 2.4; LM= Leibinger Mandible Recon

Bending: Pre = preoperative plate bending at a patient-specific model; Intra = intraoperative plate bending

Recon type: type of primary reconstruction; ap = alloplastic reconstruction; v IC = vascularized iliac crest; nv IC = non-vascularized iliac crest; v Fib = vascularized fibula

Measured distances: according to Fig. 5: A = Distance 1; B = Distance 2; C = Distance 3; D = Distance 4; E = Distance 5; F = Distance 6 (see Fig. 3)

Number measured distances: number of measured distances per operation

at the company. This printer can create a 3D model from plaster powder and a binding agent. The model is then infiltrated with a polyurethane compound to generate bone-like material properties. The costs per model were between US\$150 and US\$170 including shipping. Two to four working days expired between data upload and delivery of the model.

A total of 57 patients who underwent a partial resection of the mandible from March 2008 until August 2012 were retrospectively examined. Of these, 36 (13 women and 26 men, aged 18–87 years) were included in the study (Table 1). The inclusion criteria were as follows:

- Indication for a mandibular continuity resection.
- Preoperative and postoperative computed tomography of the entire mandible. The minimum requirement in terms of CT quality was a reconstruction with a maximum slice thickness of 2 mm.
- Availability of a minimum of two corresponding landmarks after the mandibular continuity resection (see below).

A total of 5 out of 36 patients had several parts of the mandible resected during various operations. This is why 42 operations were included in the study (Table 1). Informed consent was obtained from all patients in the study. Existing preoperative and postoperative CT scans were evaluated according to the procedure described below using IPlan[®] CMF 3.0 software (Brainlab, Feldkirchen, Germany).

A total of 22 of the 42 operations were performed using the TK-method, while the remaining 20 operations were performed according to the ST-method. Whereas the plates implanted according to the TK-method were pre-bent before surgery using a patient-specific model, this was the case in only 17 out of the 20 conventional operations (ST-method). In the other 3 cases, the plates were bent only during the operation.

All operations included in the study were performed by three highly experienced surgeons. On account of the retrospective nature of the study, the operations were distributed randomly and unevenly among the surgeons.

Where a mandibular continuity resection and reconstruction were performed in a previous operation, the CT made prior to the first operation, i.e., the CT showing mandibular continuity, was used as a reference CT. In these cases, this was also the CT that was used to fabricate the patient-specific model, which in turn served as a basis for the preformation of the mandibular reconstruction plate and for the prefabrication of the corresponding transfer keys.

Three different plate systems were used in the 42 operations included in our study:

- Matrix Mandible Recon (DePuy Synthes) $n = 32$
- Unilock 2.4 (DePuy Synthes) $n = 9$
- Leibinger Mandible Recon (Stryker Corporation) $n = 1$

All three systems are well-established, widespread angular-stable locking plate systems and no relevant differences regarding reconstruction accuracy can be supposed.

The defects caused by the mandibular continuity resection and reconstruction were divided into the following groups (Fig. 2):

- symphysis defect
- lateral body defect
- angle defect
- ramus defect
- resection of the coronoid process

The continuity defects that occurred after resection were mostly combined defects involving several of the above-mentioned areas (e.g., symphysis + lateral body defect or lateral body + angle defect). Patients who had their condyle

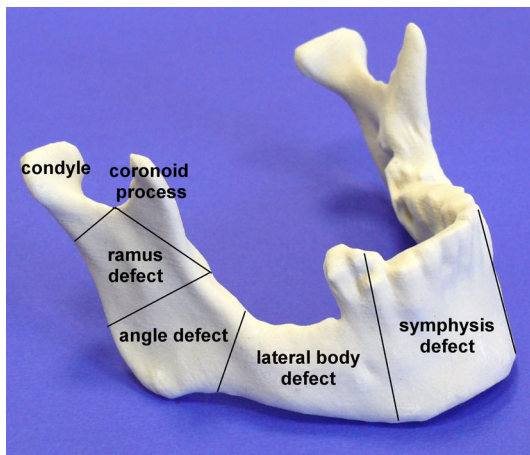


Fig. 2 Definition of defect areas after mandibular continuity resection

removed were excluded since it was no longer possible to measure two or more corresponding landmarks after such a resection. We did not differentiate between left and right sides as this was not relevant to our study. The defects listed in Table 1 occurred after the 42 operations.

The DICOM data of the preoperative and postoperative CT data sets were first imported into IPlan[®] CMF 3.0 in order to analyze the 42 operations. After the DICOM data set is converted into the software-specific XBrain format, the software uses only the axial data set to calculate both coronal and sagittal reconstructions and to display a multiplanar image. In addition, the software calculates the corresponding 3D reconstruction. In a further step, the software was used to align the preoperative data set symmetrically to the center in both the axial and coronal directions and according to the Frankfurt plane in the sagittal direction. The automatic image fusion function of the software fused the postoperative data set with the preoperative data set. The alignment of the postoperative data set thus corresponded with that of the preoperative data set in all three planes. After image fusion, the viewing mode of the software enables the user to analyze in all three planes both the preoperative and the postoperative data sets in parallel in precisely the corresponding slice.

Six corresponding landmarks (A/A', B/B', C/C', D/D', E/E', F/F') were then determined on the mandible in the preoperative CT images (Fig. 3). Based on these landmarks, six distances were measured using the distance measurement function of the IPlan[®] CMF 3.0 software.

Markers, referred to as “labeled points,” were placed at the six corresponding landmarks for measurement purposes. The distance between them was measured first in the preoperative image with the measurement function. In order to compare the distances between the preoperative and the postoperative scan, measurements were then taken in the same manner at the corresponding sectional planes of the postoperative scan and the difference between the measured distances D was calculated using the formula $D_x = D_x \text{ postop} - D_x \text{ preop}$

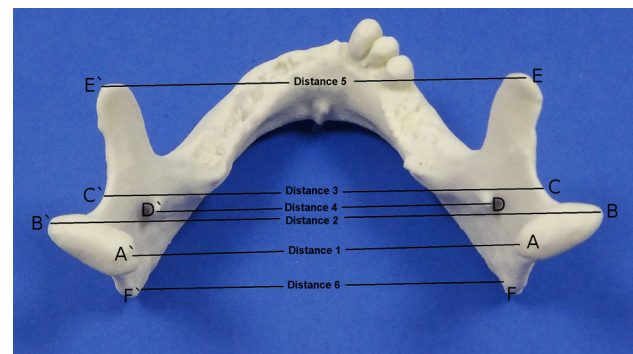


Fig. 3 Measured distances; A–A' = Distance 1 = innermost point of right mandibular condyle to innermost point of left mandibular condyle, B–B' = Distance 2 = outermost point of right mandibular condyle to outermost point of left mandibular condyle, C–C' = Distance 3 = lowest point of right mandibular notch to lowest point of left mandibular notch, D–D' = Distance 4 = tip of right lingula of the mandible to tip of left lingula of the mandible, E–E' = Distance 5 = tip of right coronoid process to tip of left coronoid process, F–F' = Distance 6 = most caudal point of right mandibular angle to most caudal point of left mandibular angle

(Fig. 4). To minimize measurement error, each measurement was independently performed three times and the mean value of the three measured values was calculated. The mean value was then taken as definitive.

A calculated value close to 0 means that the reconstruction caused a minor displacement of the rami and the condyles. Conversely, a number far from 0 indicates that the ramus and condyle positions have changed significantly as a result of the operation. Negative figures suggest a decrease in the distance, whereas positive figures are indicative of an increase.

A statistical evaluation of the calculated values was performed with Microsoft Excel 2010 (Microsoft Corporation, Redmond, USA) and SPSS Statistics for Windows 15.0 (International Business Machines Corporation, Armonk, USA). In addition to descriptive statistics, data were tested for normal distribution using the Shapiro–Wilk test, and a Mann–Whitney test was performed to compare the ST-method with the TK-method. Values of $p \leq 0.05$ were considered significant and values of $p \leq 0.005$ highly significant. Bonferroni correction was used to adjust the significance level for single-distance comparisons to $p \leq 0.003$.

In addition to the above-mentioned radiological evaluation, pre- and postoperative occlusion was also clinically evaluated. A distinction was made between:

- clearly identifiable stable occlusion before and after surgery,
- not clearly identifiable unstable occlusion before and after surgery and
- postoperative malocclusion.

“Not clearly identifiable unstable occlusion” refers to edentulous patients, patients with no occluding tooth pairs, with

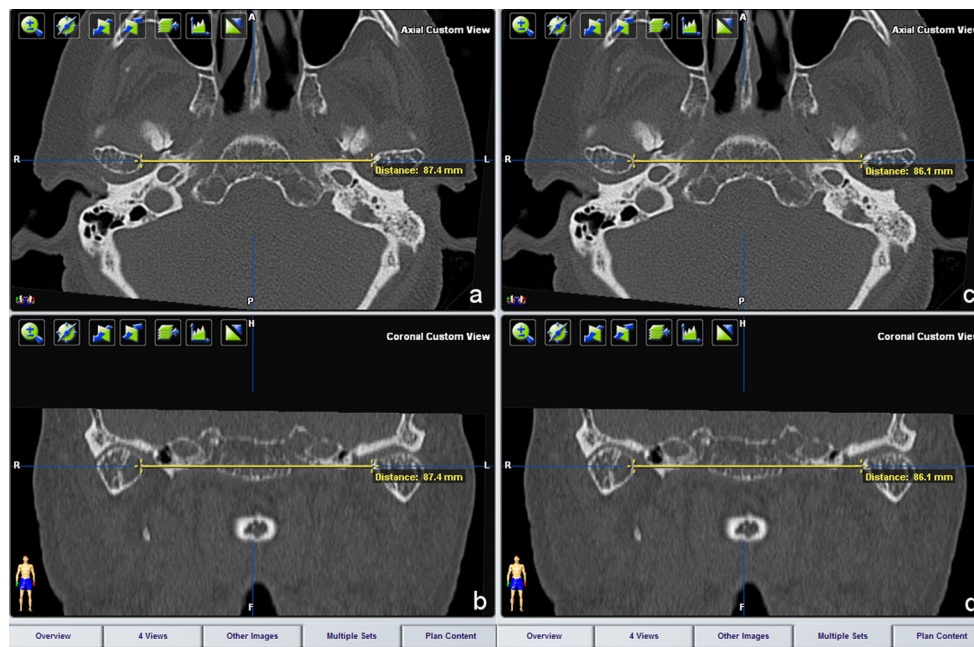


Fig. 4 Measurement of distance between the innermost points of the left and right condyles in iPlan® CMF 3.0. Left preoperative CT image, **a** shows axial plane, **b** shows coronal plane. Right postoperative CT image, **c** shows axial plane, **d** shows coronal plane. The yellow lines

are representing the lines joining the pre- and postoperative innermost points of the left and right condyles, the yellow numbers are the length of the yellow lines calculated by the program

only up to three occluding tooth pairs in the lateral tooth area, or with only up to four occluding tooth pairs in the anterior tooth area. Definitions of “postoperative malocclusion” and “clearly identifiable stable occlusion before and after surgery” are omitted here since they are self-explanatory.

Results

Measurement results

Since in some cases parts of the mandible with corresponding landmarks had been resected, it was not always possible to measure all 6 distances in each of the operations. Nevertheless, a total of 203 distance measurements were carried out between corresponding landmarks. All 6 distances could be measured after 21 of 42 operations, 5 distances after 7 operations, 4 distances after 2 operations, 3 distances after 10 operations and only 2 distances after 2 operations (Table 1).

A comparison of the unsigned/absolute values of all differences between preoperative and postoperative distances 1–6 reveals an advantage of the TK-method over the ST-method. Detailed data are listed in Table 2. It must be taken into account, however, that the number of operations ($n = 3$) with plates bent during surgery is very low.

As illustrated in Table 4, the Mann–Whitney test revealed more accurate results for the TK-method in comparison with the ST-method.

Signed values were compared in order to evaluate whether the operations caused an increase or decrease in the distances measured. The results of these measurements are shown in Table 3. In general, the operations resulted in a decrease in distances and thus a compression of the mandible in the ramus and joint areas. According to our study, however, this phenomenon is less apparent when the TK-method is used.

A Mann–Whitney test that compared the signed distances of the TK- and ST-methods showed no significant difference between these two methods (Table 4).

If we look at each of the 6 measured distances individually, the above-mentioned results are brought into perspective. Table 5 shows the detailed data of the unsigned/absolute and signed deviations of the postoperative distances in comparison with the preoperative distances for each operation method (TK- or ST-method).

An examination of the unsigned/absolute values reveals that, except for distance 6, the median deviation was smaller for the TK-method than for the ST-method. A statistical evaluation by way of the Mann–Whitney test and Bonferroni correction did not show a significant advantage of any method (Table 4). Nevertheless, a tendency in favor of the TK-method cannot be denied.

An examination of the signed deviations of the 6 distances measured shows, much like the overall analysis, that a decrease in the distances in the ramus and jaw joint area occurred in our study. Distance number 5 using the ST-method was one exception to this rule only (Table 6). Like

Table 2 Unsigned/absolute values of the differences between all preoperative and postoperative distances

	Number of operations	Number of measurements	Median (mm)	Max (mm)	Min (mm)	Range (mm)	Interquartile range (mm)
TK	22	116	1.07	9.93	0.03	9.9	1.77
ST (preop)	17	76	1.67	9.9	0.03	9.87	1.9
ST (intraop)	3	11	2.03	4.6	0.6	4	2.13
ST (total)	20	87	1.67	9.9	0.03	9.87	2.03

TK = transfer key method, ST (preop) = standard method with preoperatively bent plates, ST (intraop) = standard method with intraoperatively bent plates, ST (total) = total operations performed according to the standard method

Table 3 Signed values of the differences between all preoperative and postoperative distances

	Number of operations	Number of measurements	Median (mm)	Max (mm)	Min (mm)	Range (mm)	Interquartile range (mm)
TK	22	116	-0.6	4.73	-9.93	14.67	1.95
ST (preop)	17	76	-1.23	3.67	-9.9	13.57	3
ST (intraop)	3	11	-2.03	1.3	-4.6	5.9	2.6
ST (total)	20	87	-1.47	3.67	-9.9	13.57	3.2

TK = transfer key method, ST (preop) = standard method with preoperatively bent plates, ST (intraop) = standard method with intraoperatively bent plates, ST (total) = total operations performed according to the standard method

Table 4 *p* values of Mann–Whitney tests for comparison of the TK-method with the ST-method for all six distances together and for the six distances individually

	Unsigned/absolute values		Signed values					
	TK versus ST total (<i>n</i> = 22:20)	TK versus ST preop (<i>n</i> = 22:17)	TK versus ST total (<i>n</i> = 22:20)	TK versus ST preop (<i>n</i> = 22:17)	TK versus ST total (<i>n</i> = 22:20)	TK versus ST preop (<i>n</i> = 22:17)		
Distance 1	0.002**	0.044#	0.006*	0.133#	0.062#	0.308#	0.214#	0.702#
Distance 2		0.037#		0.077#		0.332#		0.650#
Distance 3		0.128#		0.070#		0.472#		0.490#
Distance 4		0.546#		0.663#		0.204#		0.271#
Distance 5		0.020#		0.031#		0.358#		0.504#
Distance 6		0.399#		0.193#		0.429#		0.651#

Distances 1–6: see “Methods” section as well as Fig. 3

TK versus ST total = comparison of TK-method and all ST-method approaches

TK versus ST preop = comparison of TK-method and ST-method with plates bent preoperatively on a patient-specific model

p values are given for the evaluation of differences with regard to their significance for all 6 distances together and for individual distances:

p ≤ 0.005 = highly significant (**); *p* ≤ 0.05 = significant (*); *p* > 0.05 = no significance (#)

Significance level for single-distance comparisons was set to *p* ≤ 0.003 after Bonferroni correction

the overall analysis, a Mann–Whitney test did not reveal a significant advantage for any method with regard to relative deviations (Table 4).

A linear correlation between the defect sizes caused by the operations and the deviations of the 6 distances measured after surgery could be identified neither for all measurements together nor for the TK-method and the ST-method individually. The individual measurement results are therefore not presented.

Evaluation of postoperative occlusion

In 14 of the 42 operations that were included and measured in our study, temporary maxillo-mandibular fixation (MMF)

was performed during the operation since at the time of reconstruction the patients still had an identifiable occlusion. In 12 of these 14 cases, it was possible to achieve a “stable, identifiable occlusion”. In two cases, the occlusion could not be evaluated due to extensive scarring and restricted mouth opening and was therefore assessed as “postoperative malocclusion”. Of the 12 cases with “stable, identifiable occlusion”, 4 were operated on according to the TK-method and 8 according to the ST-method. In 6 of the 8 ST-method cases, a pre-bent plate was used and in 2 cases the plate was bent during the operation. With regard to the 2 remaining cases in which the occlusion could not be reliably assessed after the operation and which were therefore deemed to be malocclusions, one operation was performed according to the TK-method and

Table 5 Unsigned/absolute values of the differences between the six pre- and postoperative distances

	Number of measurements	Median (mm)	Max (mm)	Min (mm)	Range (mm)	Interquartile range (mm)
Distance 1						
TK	22	0.82	4.8	0.1	4.7	1.44
ST (total)	20	1.63	3.97	0.43	3.53	2.02
Distance 2						
TK	22	1.08	5.43	0.1	5.33	1.74
ST (total)	20	1.85	7.57	0.43	7.13	1.96
Distance 3						
TK	21	0.87	5	0.03	4.97	1.18
ST (total)	18	1.57	4.8	0.1	4.7	1.83
Distance 4						
TK	19	0.5	3.33	0.03	3.3	1.7
ST (total)	11	1.57	2.8	0.03	2.77	1.4
Distance 5						
TK	16	1.2	6.6	0.1	6.5	2.21
ST (total)	8	2.9	9.9	1.3	8.6	1.67
Distance 6						
TK	16	1.9	9.93	0.03	9.9	2.3
ST (total)	10	1.5	4.67	0.07	4.6	2.1

Table 6 Signed values of the differences between the six pre- and postoperative distances

	Number of measurements	Median (mm)	Max (mm)	Min (mm)	Range (mm)	Interquartile range (mm)
Distance 1						
TK	22	-0.67	4.73	-4.8	9.53	1.33
ST (total)	20	-1.58	1.9	-3.97	5.87	3.26
Distance 2						
TK	22	-1.05	2.97	-5.43	8.4	1.73
ST (total)	20	-1.57	2.13	-7.57	9.7	3.57
Distance 3						
TK	21	-0.63	2.53	-5	7.53	1.83
ST (total)	18	-0.85	2.03	-4.8	6.83	3.45
Distance 4						
TK	19	-0.1	3.33	-3.03	6.37	1.93
ST (total)	11	-1.57	0.73	-2.8	3.53	1.43
Distance 5						
TK	16	-0.12	2.87	-6.6	9.47	2.45
ST (total)	8	1.53	3.67	-9.9	13.57	6.29
Distance 6						
TK	16	-0.33	3.67	-9.93	13.6	4.29
ST (total)	10	-1.5	1.13	-4.67	5.8	2.73

TK = transfer key method, ST (total) = total operations performed according to the standard method. Distances 1–6: see “Methods” section as well as Fig. 3

the other according to the ST-method. As a result, neither method had an apparent advantage.

In the remaining 28 cases, the patients did not have “stable occlusion” at the time of surgery or after the continuity resec-

tion, which is why reconstruction could not be performed with temporary MMF. At the time of surgery, 12 of these patients were edentulous, 9 patients had no occluding tooth pairs, 3 patients had only up to three occluding tooth pairs

in the lateral tooth area and 4 patients had only up to four occluding tooth pairs in the anterior tooth area. Of these 28 cases, 17 were operated on using the TK-method and 11 using the ST-method. In only one of the 11 ST cases was an intraoperatively bent plate used, whereas in 10 cases, the plates were already pre-bent using a model.

Discussion

When all 6 distances were assessed together, our study revealed a significantly more accurate reconstruction outcome with regard to unsigned/absolute deviations for the TK-method presented here than for the ST-method. If, however, we look at each of the 6 distances individually, we see only a tendency toward a more accurate reconstruction outcome. Nevertheless, it is clear that the reconstruction outcome of the TK-method is not less accurate than that of the ST-method. This finding is more or less consistent with the finding of the *in vitro* trial of Wilde et al. that also compared the TK-method with the standard method on models [6].

We believe that the unsigned/absolute deviations also represent the absolute accuracy of the two methods we compared. They do not, however, provide information about the direction of the deviation. This is expressed by the signed outcome (see below). One potential reason for the higher inaccuracy of the ST-method compared to the TK-method could primarily be a minimal elastic deformation of the reconstruction plates when they were first screwed onto the bone before the mandible resection. When the plate is rescrewed onto the stumps after the continuity resection, it returns to its initial bent form, which results in a positional change of the bone stumps compared to the preoperative position. Moreover, it is conceivable and possible that the screw holes drilled before the resection and used for the primary fixation have changed as a result of this process so that when the reconstruction plate is again fixed, the screws are inserted in a slightly different position.

If we compare the unsigned/absolute values of the group of patients operated on according to the ST-method with pre-bent plates and those patients whose plates were bent during the operation, it can be seen that reposition accuracy is greater for pre-bent plates (Tables 2, 3, 4, 5, 6). The number of cases with intraoperatively bent plates is, however, very low ($n = 3$) and is therefore only to a limited extent comparable to the group of patients with pre-bent plates. It can nevertheless be said and is confirmed by other studies [6, 10, 12–14] that pre-bending mandibular reconstruction plates on patient-specific mandible models has clear advantages when it comes to the accuracy of reconstruction outcome.

Transfer keys cannot prevent a positional change of the condyles and the ascending rami. Here, too, there are various explanations. As mentioned above, the main cause could be that when the plates were pre-bent on the patient-specific

model prior to surgery, they were not bent accurately enough. As a result, they were not completely free of tension on the model when the transfer keys were produced. When the plate was repositioned after mandibular continuity was interrupted, there was a shift of the resected mandible stumps in the ramus and condyle area. The inaccurate positioning of the transfer keys on the mandible could also play a role. In our data, we could see considerably more outliers with the TK-method than with the ST-method. This may be caused by occasional clinical difficulties in positioning transfer keys. Greater inaccuracies in mandible reconstruction thus result if transfer keys cannot be positioned accurately. This problem cannot be seen to this extent with the ST-method. In addition to positioning inaccuracy, the inaccuracy of transfer keys themselves may also have a negative effect. This can be explained by the inaccuracy of the model used to fabricate the keys and by the inaccuracy of the material of the transfer keys. The transfer keys used in this trial were made of light-curing resin that is known to shrink during the curing process. Furthermore, transfer keys must be sterilized for surgery, which may further alter their form and size. This impact could possibly be eliminated by manufacturing the keys using CAD/CAM technologies [6]. If we consider, however, the actual deviations encountered in our study in mm, we can conclude that these deviations are probably of minor importance with regard to their clinical relevance. Unfortunately, we were unable to find comparable data in the literature which indicate when deviation is clinically relevant. From our perspective, however, we believe that this is different from case to case, but we also believe that reconstruction that is as accurate as possible is the best way to reduce functional sequelae.

If we consider the results of our study with regard to signed deviation, we must assume that both methods, as evidenced by the decrease in the measured distances, tend to lead to a compression of the mandible in the ramus and condyle area. However, an increase is also possible. This finding is different from the finding of the *in vitro* study of Wilde et al. [6], in which measured distances tended to increase. One possible explanation could be that the plates in the *in vitro* study were bent and screwed onto the model by a single person, while the plates in the clinical study presented in this paper were bent and implanted by various surgeons.

The compression in the ramus and condyle area can easily be explained by the fact that the plates tend to be under tension when they are bent on the patient-specific models. When mandibular continuity is interrupted, the tension is eliminated and the compression mentioned above inevitably occurs. On the other hand, if the plate is not fully bent on the model, extension in the ramus and condyle can occur.

In addition to the one-dimensional shifts we measured and have described here, 3D shifts are more likely. Such shifts are very difficult if not impossible to detect with our

methodology. They are, however, reflected by the individual values measured for each patient. If there were only a one-dimensional shift, all values would have to deviate in the same direction over approximately the same distance. This, however, is not the rule. Nevertheless, we believe that the fundamental statements made above with regard to reconstruction accuracy are tenable, in particular on the basis of the unsigned/absolute distances we examined. These values do not take into consideration whether there is a decrease or an increase in the measured distances but only show the absolute postoperative deviation from the initial value.

If we consider the clinical practicability of the two methods rather than their accuracy, the following statements can be made. The relatively large amount of time and effort (around 20 min) involved in the fabrication of the transfer keys is one disadvantage of the TK-method. In addition, it can be quite difficult to position transfer keys during surgery. This applies in particular to the high condyle, as it is difficult to see during surgery, and surprisingly the lateral body of the mandible. Problems in the lateral body of the mandible result from its smooth surface and lack of edges, which make it difficult to position transfer keys precisely. In everyday hospital practice, this can lead to delays and inaccuracies when it comes to positioning. It is possible, however, to counteract this problem by making the contact surface between the transfer key and the bone as large as possible and by including the mandibular notch near the condyle and the mental foramen as points of reference in the lateral body of the mandible. In contrast, the positioning of transfer keys in the area of the angle of the mandible and the chin is usually simple, fast and unproblematic. If possible, these sites should be preferred as points of reference for the fabrication of transfer keys.

As clinical experience shows, the ST-method in combination with preoperatively bent plates appears to yield satisfactory surgical results with regard to repositioning accuracy and at the same time reduces surgical procedure times by between 30 and 90 min (depending on the case and the experience of the surgeon) [6, 14].

As already mentioned in the introduction, the ST-method, however, has limitations or cannot (in contrast to the TK-method) be used if the mandibular outer cortex is involved in the malignant, pathological process that necessitates the resection and if a safe resection with an adequate safety margin is possible only if the tumor is resected without prior plate adaptation [10]. The ST-method also cannot be used if the surgeon favors a plate shape that does not correspond to the outer cortex. In our view, such plate shapes are recommended and desirable for a great number of patients and were used in all patients who were operated on according to the TK-method. One example in this context is the use of an undercontoured plate in the chin area. An undercontoured plate may prevent or slow down the perforation of the skin by

the plate, especially in the case of alloplastic mandible reconstruction. In addition, undercontouring usually contributes to an aesthetically favorable result since the plate appears less bulky and a prominent chin can thus be avoided.

In the case of primary or planned secondary osseous mandible reconstruction with possible subsequent implantation, it is generally desirable to plan a plate contour that is more medial than the outer contour of the original mandible. This applies in particular to the molar region [24].

From a technical point of view, the approach favored in both examples can easily be taken by removing material from a specific part of the patient-specific model, for example from the chin or the lateral mandibular body region, with a burr and by pre-bending the plate with the help of the modified model. The TK-method makes it possible to transfer the plate position from the model to the surgical site (Fig. 1) [6].

A further case in which the ST-method is of limited use is the implantation of a primary microvascular bone graft (e.g., fibula, iliac crest, scapula). It is possible to shape the plate to the outer contour of the mandible to be resected, to fix the plate according to the ST-method and to screw the bone graft onto the plate. In most cases, however, attaching the graft to the plate is feasible only with great difficulty and at a large distance to the plate. In this case, too, the TK-method may be useful. In these cases, either the shape of the patient model can be changed to reflect the intended position of the bone graft, or the reconstruction can be planned virtually before a corresponding model is built. The reconstruction plate is pre-bent on this model and then, using the transfer keys, positioned on the remaining mandibular stumps during surgery in accordance with plans. The bone graft can then be screwed to the plate with good a fit and a high degree of accuracy in an acceptable amount of time (Fig. 5).

In all the cases mentioned here, the TK-method presented in this study is a possible option for tackling these problems in a relatively easy and uncomplicated manner.

As part of a case report, Hallermann et al. [1] describe a method that is nearly similar to the TK-method. A mandibular reconstruction plate was also pre-bent before surgery on a patient-specific mandibular model and fixed onto it with the help of small clamps. Afterward, the model was covered with silicone dental impression material so that an impression of both the plate and the mandibular angles was made. With the help of this impression, the plate was positioned during surgery in accordance with the position on the model. We are convinced, however, that such impressions can easily slip out of position and that, on account of their deformability and flexibility, the plate cannot be positioned as accurately as with transfer keys made of plastic. Hallermann et al. also fail to mention if and how silicone impressions can be sterilized for surgery. In addition, the publication does not contain a postoperative evaluation of reconstruction accuracy.

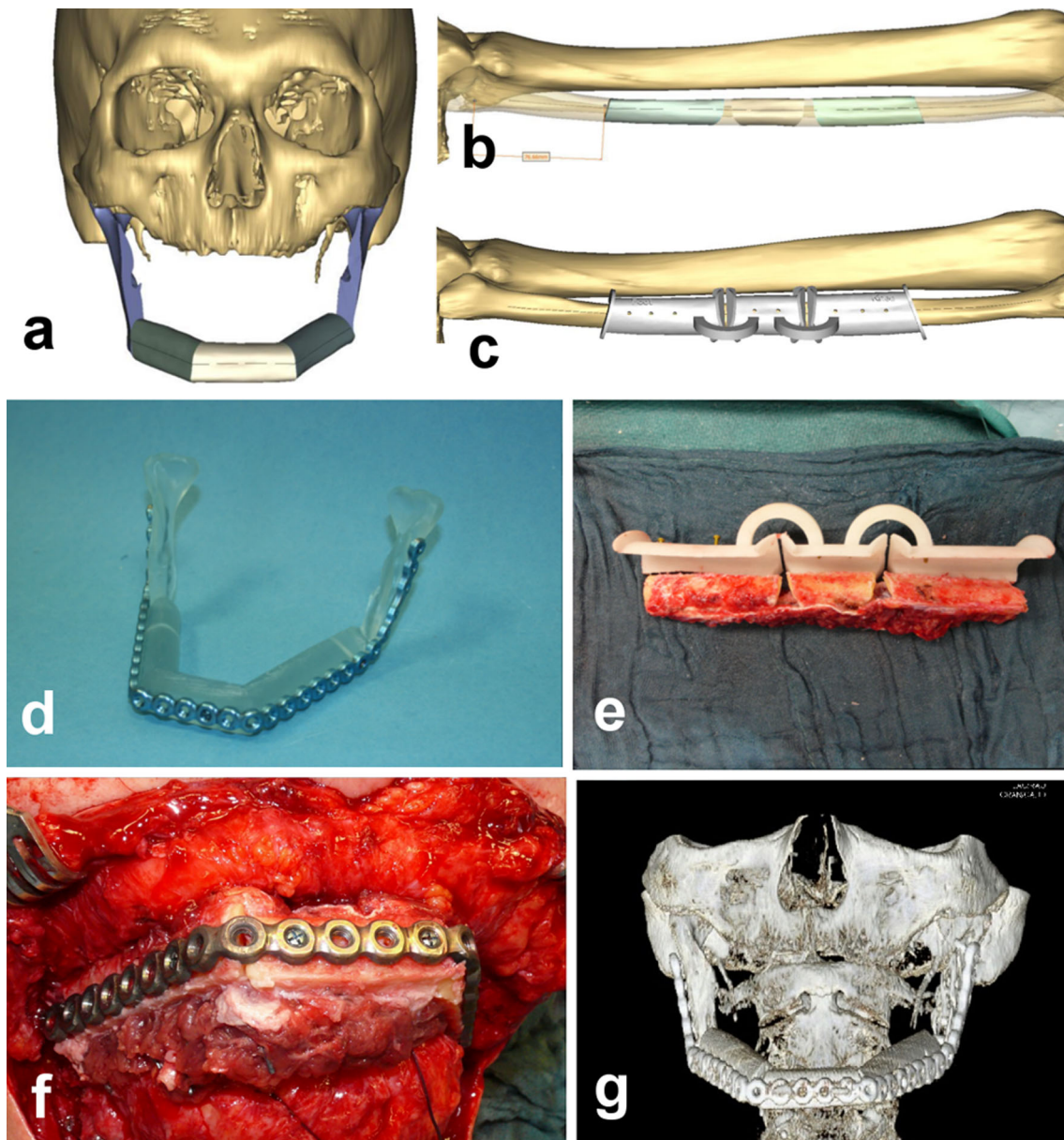


Fig. 5 Computer-assisted secondary mandible reconstruction with pre-bent reconstruction plate positioned on the remaining bone stumps using transfer keys. **a** Patient-specific virtual reconstruction of the mandible with a fibula graft. **b** Virtual planning of the fibula osteotomies regarding the reconstruction plan (**a**). **c** Computer-assisted design (CAD) of the “cutting templates” for the fibula osteotomies. **d** 3D model

A method published in early 2014 described the transfer of the virtually planned position of a CAD/CAM titanium reconstruction plate to a surgical site during computer-assisted mandibular reconstruction. To this end, drill sleeves were incorporated into resection guides which transferred the exact position of the holes in the CAD/CAM titanium reconstruction plate from the virtual position to the surgical site. The holes drilled with the help of these guides were then used to fix the titanium reconstruction plate in the planned position on the remaining mandibular stumps [25]. This study, how-

ever, used only one corpse, and thus, a clinical evaluation was not made.

We believe that other methods such as the splint and plate technique of Reece [20], external fixation methods [10, 15, 16, 18, 19], modified methods based more or less on external fixation [17, 23] and the Kirschner wire method (K wires) [21] are complicated in comparison with the method presented here and are often applicable only to a limited extent. In addition, these publications do not contain any valid information about the accuracy of these methods since

the majority describe individual cases or small case groups without control groups.

MMF is certainly one option for stabilizing the mandible during surgery. As in this study, however, most patients who have to undergo a mandibular continuity resection are partially or completely edentulous. This condition usually rules out such a procedure.

Conclusions

The study presented in this paper shows that the TK-method for mandible reconstruction using mandibular reconstruction plates produces more accurate reconstruction results than the ST-method when carried out correctly and carefully. It is an effective method with sufficient clinical accuracy particularly for patients who cannot be treated with the ST-method on account of the clinical situation.

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